Memo of Meeting

Date: August 28, 2002

Representing Agile Software, Inc.:
San Jose, CA

Marcus Yoder, Director Medical Device Industry
Deron Jordan, Solution Consultant

Representing US Data Management
Oxnard, CA

Ms. Stepheni Bodo, Project Manager, Business Systems

Representing FDA:

Charles Snipes, Compliance Officer, Center For Drug Evaluation and Research
Randall L. Woods, Consumer Safety Officer, Center For Drug Evaluation and Research
George Smith, Consumer Safety Officer, Center For Drug Evaluation and Research
John Murray, Software Expert, Center For Devices and Radiological Health
Paul J. Motise, Consumer Safety Officer, Office of Enforcement

The meeting was held at the request of the Agile Software representatives, to discuss their product lifecycle management software offered to FDA regulated industries (in particular medical device establishments) in the context of 21 CFR Part 11. At the start of the meeting we explained that FDA does not formally review, approve or disapprove of products or services that enable people to comply with FDA regulations. We advised that the meeting would be an information exchange and that our comments should not be taken as formal FDA positions.

The Agile Software representatives described their offering as a product lifecycle management application. The system is not a process control application but a document management system. They explained that US Data Management is a business partner that helps customers with system validation activities. Medical device firms regulated by FDA constitute the second largest industry group among their customers; most of their customer base is in the electronic high technology sector.

The Agile Software representatives explained that their system runs on PC based computing platforms, either as stand alone or as web based where the application resides on a server that can be accessed over the Internet by a web browser. The application is configured on top of Oracle and an instance of Oracle is included in the software. The system has four primary modules (product collaboration, sourcing, service & improvement, and program execution) that are offered separately or in combination.

During the meeting we discussed the appropriateness of representing software as "part 11 compliant". We explained that the term is a misnomer because people who are subject to part 11 are responsible for compliance with the rule and because achieving compliance involves implementing a collection of administrative, procedural and technical controls. We suggested that where software has technical features that are required by part 11, it would be appropriate to map those features to particular part 11 controls and then let prospective customers determine for themselves the potential suitability of the software in their own circumstances.

During the meeting the Agile Software representatives gave us a brief case history where their system was in use by a medical device producer. They also gave us a brief demonstration of their software in managing medical device master records. We noted that the system displays the software name and version designation in the functioning windows.

We discussed how the system might be able to generate electronic copies of electronic records for FDA field investigators. The system produces copies based on XML under the PDX (product data exchange) format. The Agile Software representatives explained that the PDX format was non-proprietary, but that one would need a PDX viewer application (free download available) to read the e-record. Processing of information in the PDX viewer was limited and is not the same as could be attained by the native Agile Software used to produce the original electronic record. We explained our concerns regarding this limitation and the disadvantage to our investigators of having to work with multiple quasi-proprietary format e-records to do their work. We commented that FDA would be addressing e-copies in an industry guidance and that all interested parties would have an opportunity to comment.

We also discussed the possibility of FDA web based authorized access to a device firm's system. We commented that firms might be concerned about inadvertent FDA access to information we were not authorized by law to inspect, and FDA personnel would have concerns about being given access to highly filtered information that may be a subset of what we are authorized to inspect. The Agile Software representatives explained that access is possible via role-based access restrictions.

Regarding electronic signatures, the system uses identification codes in combination with passwords. Signature passwords must be separate and distinct from system log-in passwords. The software provides system administrators with password configuration options including password length (the default is set to 6 characters), composition, expiration periods, recycling and inactivity time-outs. Electronic signatures in electronic records are manifest in their human readable forms by display of the signer's printed name, date/time of signing and what the signature means.

During the meeting we discussed the system's audit trailing features. The system's audit trail records who (by operator's printed name) wrote, modified or deleted what electronic records and the date and time (local to system server as well as operator) of those actions. The system also records who accessed system records.

During the meeting we discussed the firm's validation efforts. The representatives said they would welcome, and have undergone, customer audits of their software development activities. The firm provides test scripts. In addition, the firm's partner, US Data Management, provides documentation examples and templates to help end users perform their validation. These include, but are not limited to, validation protocols, user acceptance testing, system specification and design templates for risk assessments and user requirements. In addition, the firm's partner, US Data Management, provides documentation examples and templates to help users perform end user validation.

The meeting lasted about two hours.

cc:
FDA Attendees
HFA-224
Part 11 Guidance Dockets

Doc ID AgileSoftwareMemoOfMeeting082802.doc
P. Motise 08/29/02, rev 10/11/02